FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Product Constituents Subcommittee

of the

Tobacco Products Scientific Advisory Committee (TPSAC)

Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD

June 8-9, 2010

Agenda

The subcommittee will receive presentations and discuss the development of a list of harmful or potentially harmful constituents, including smoke constituents, in tobacco products. Topics for discussion will include the criteria for selection of the constituents, developing a proposed list of harmful or potentially harmful constituents, the rationale for including each constituent, and the acceptable analytical methods for assessing the quantity of each constituent. A second meeting of this subcommittee, to continue these discussions as necessary, and to include ancillary and normalization standards for the constituents, will be scheduled for the summer of 2010.

June 8, 2010

Call to Order	Dorothy Hatsukami, Ph.D. Chair Tobacco Product Constituents Subcommittee
Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Designated Federal Official, FDA
Introduction of Subcommittee Participants	
Charge to the Group: Harmful and Potentially Harmful Tobacco Product Constituents	Corinne Husten, M.D., M.P.H. CTP
Clarifying questions	
Examples of Lists of Harmful/Potentially Harmful Constituents and the Rationale for Inclusion	Patricia Richter, Ph.D. Office on Smoking and Health National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention
Clarifying questions	

Industry Presentations: Preliminary Information Concerning the Establishment of a List of Harmful and Potentially Harmful Tobacco Product Constituents

Michael W. Ogden, Ph.D.
R. J. Reynolds Tobacco Company
(On behalf of multiple tobacco product manufacturers)

David Michael Johnson, Ph.D.
Council of Independent Tobacco Manufacturers of America (CITMA)

Clarifying questions to Industry

Lunch

Carcinogen Classification Criteria — Patricia Richter, Ph.D.

Subcommittee Discussion of Criteria for Determining Initial List of Harmful/Potentially Harmful Constituents

Open Public Hearing

Proposed Methodology Options for Analysis of Constituents — Clifford O. Watson, Ph.D.
National Center for Environmental Health
Centers for Disease Control and Prevention

Subcommittee Discussion and Development of List of Harmful/Potentially Harmful Constituents

Adjourn

June 9, 2010

Call to Order — Dorothy Hatsukami, Ph.D.
Chair
Tobacco Product Constituents Subcommittee

Conflict of Interest Statement — Karen M. Templeton-Somers, Ph.D.
Acting Designated Federal Official, FDA

Subcommittee discussion on list of harmful/potentially harmful constituents, rationale, and proposed methodology

Methodologies used to Develop Toxicology Summaries — Patricia Richter, Ph.D.

Lunch

Subcommittee discussion and development of harmful/potentially harmful constituents, rationale, and proposed methodology

Finalize draft list of harmful and potentially harmful constituents

Subcommittee discussion of the Questions to the Subcommittee

Adjourn